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American Agricultural Services Inc.

February 25, 2002

United States Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460

Subject: Comments on the Cross Media Electronic Reporting and Recordkeeping Rule (CROMERRR)

Dear Sir/Madam:

We are writing to you in response to the proposed CROMERRR Rule as published in the Federal Register on August 31, 2001. Due to the far reaching scope of this proposed rule and our concerns over several issues raised by this rule, American Agricultural Services, Inc. (AASI) feels it is necessary to provide comment to the EPA prior to publication in its final form. We are addressing our comments from the point of view of a CRO company involved in the management of GLP studies in the AgChem sector and as a software producer for use in conducting GLP studies for EPA submission.

The points below address our main concerns & issues with the CROMERRR proposed rule.

1. **Cost to Facilities:**
Even though it is stated in the rule that it is voluntary, if facilities are already collecting data electronically as part of their normal procedures they will be subject to CROMERRR. If they do not want to deal with the regulations concerning electronics they would have to stop using their electronic systems altogether and to go to a manual type of system. This would remove whatever efficiencies they gained by using the electronics and cost them additional money and time to implement the new procedures. If they elect to continue using their electronic systems (either because they don't want to lose the efficiencies or the electronic systems cannot be removed from their procedures & facilities), they will incur considerable cost to upgrade these systems to bring them into compliance with CROMERRR, if that is even possible. Many of the instruments used by Field Contractors do not have the components (audit trail, metadata collection, electronic signature, security) to be in compliance with CROMERRR and it is not likely that all the manufacturers of these pieces of equipment will offer updates or upgrades to bring these devices into compliance. If the manufacturers were willing to produce a product that is, or is close to being, CROMERRR compliant, the cost of equipment & software would increase substantially, and probably to the point where it would not be possible for the Field Contractor to afford these devices & software. While we see the need to provide data that is reliable, secure and reproducible we are concerned that data that has been

considered acceptable by the EPA for years in support of pesticide registrations will now become unacceptable and will cost the Field Contractors and Analytical Laboratories tremendous amounts of money to produce the same data. These very large expenditures that will be necessary for facilities to become compliant with CROMERRR we feel will cause many facilities to move away from the use of electronics, which is contrary to the goals of the Paperwork Elimination Act , and/or may force smaller facilities out of business. We realize that the cost of doing business in a regulated environment means accepting that at times there will be additional costs for staying in this business. However, we feel that these costs are extremely high for this industry, will actually inhibit the use of better scientific practices and will reduce gains that could be made through the use of electronics.

2. **Lack of Clear Definitions:**
Another concern with the Rule is that it does not give clear definitions of some of the key terms used throughout the Rule. Some of these terms are raw data, records, metadata and differences between audit trail & metadata. We agree that some ambiguity in a document is a good thing in that it allows for different interpretations to reach the same goal but, the lack of clear definition in some of the most basic terms makes it difficult to know how to apply the principles of the rest of the rule.

3. **Archival of Data & Systems:**
This is another major concern for any entity involved in conducting GLP studies because of the long record retention requirements for data/records created in support of a pesticide registration which may often be 25 or more years. Software is constantly being upgraded to improve the quality of the product, to meet customer demands and to keep up with changes/advances in hardware & operating systems. Sometimes it is the improvements in software capabilities that drive the need for more powerful operating systems with expanded capabilities. More powerful operating systems with expanded capabilities means that software must be updated/expanded to keep up with ever expanding systems. Software and systems are forever linked in this cycle that as one grows the other must keep up. As such, getting support for a product more than a couple of years old is very difficult. Products more than 5 years old are rarely supported by manufacturers. So, if you are a company producing and/or capturing data electronically that will be used in support of a pesticide registration you will be faced with (under CROMERRR) keeping that data in electronic format for the lifetime of that pesticide registration which it supports. Typically the pesticide registration will be maintained for at least 25 years and may be as long as 50 years. In an environment where the computer systems and software are only supported for about 5 years it is nearly an impossible task to maintain both the data and the software and hardware necessary to reproduce that data electronically. Even if the producer of the data did try to archive the hardware, software (version used to collect data) and the data files themselves there is no guarantee that the system will even be functional in 10 years much less 25 years. Parts for the hardware will probably not even be available if the hardware should become defective. The rule must allow that at some point the facility producing the data or the Sponsor must be able to migrate that data to another electronic system (if even possible) or print out the data on paper for long term storage and review of this data. Trying to maintain data electronically long term with access by the same system(s) that produced/recorded it is just not a feasible requirement. Even if it were possible the cost of trying to maintain these systems and then migrate all this data forward at some point in the future would be enormous. This has already been witnessed by companies operating under FDA's 21 CFR Part 11. OECD allows transfer of the electronic data to paper for studies submitted to the

European Regulators. Any rule for electronic data must allow for transfer of electronic data to another medium at some point. Otherwise, the cost of trying to maintain this data electronically may prohibit the use of many electronic data capture systems and this is assuming that this will even be possible to do in the first place.

4. **Requirements for Security in Electronic Systems far More Restrictive than for Paper Systems:**
While AASI realizes the need for security and fraud prevention in electronic systems, these rules should not greatly exceed those used for paper and should definitely not penalize the entity for using electronics. The requirements in CROMERRR for electronic data/records appear to exceed all those requirements previously utilized in systems using only paper or a combination of electronics & paper as the recording media. If fraud is the real concern here, it must be realized that both electronic and paper systems can be fraudulently altered. No matter how secure a system is someone that really wants to can break into the system and bypass the security measures in place. However, this is probably harder to do without leaving some sort of trail in an electronic environment than with paper. A paper document may be simply recreated and the original discarded. Again, we would like to point out that we at AASI understand the need for audit trails and security in any electronic system but the requirements need to realistically address this before a rule such as CROMERRR is put in place.

Many other items have been addressed at the public meetings by documents provided to EPA by Dow Chemical Company, BASF, British Petroleum and others. The above are the major items we wanted to note to EPA. Our major reason for commenting to EPA is to get EPA to consider stopping the finalization of the CROMERRR Rule until these and other items can be resolved. If it is not possible to stop the issuance of CROMERRR because of deadline requirements to comply with the Paperwork Elimination Act (GPEA), then at least the removal of the Record Keeping section (Subpart C) from the Rule must be considered. This section could be removed from the current rule and then issued as a separate document at a later date when many of these issues have been resolved.

If you have any questions concerning this response you may address them to AASI Management at the address or phone numbers indicated on letterhead. AASI would hope that EPA would at least remove the record keeping section from the rest of the CROMERRR Rule before it is finalized and enacted into law. We at AASI would be willing to work with EPA as part of an industry working group or task force to revise the record keeping section of this rule to make it a practical document and a document that helps to assure the validity of the data produced/captured by electronic systems.

Best Regards,

Lafayette Thompson, Jr., Ph.D.
President